

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
ANTIVIRAL DRUGS ADVISORY COMMITTEE
Marriott Washingtonian Center, Gaithersburg**

**DRAFT ADVISORY COMMITTEE AGENDA
October 16, 2000**

Topic: Discuss the Use of Surrogate Markers in the Early Development of Immunomodulatory Agents for the Treatment of Patients with Human Immunodeficiency Virus (HIV).

- 8:30 Call to Order, Introductions** Henry Masur, M.D., Chair
Conflict of Interest Meeting Statement Nancy Chamberlin, Exec. Sec.
Opening Remarks William D. Schwieterman, M.D.
- 8:40 Need for New Therapies** Lawrence Fox, M.D., Ph.D.
- 9:00 Need for Well-Characterized Biomarkers and Surrogate Markers** Jay P. Siegel, M.D.
- 9:15 Biomarkers and Surrogate Markers in Product Development**
- An Overview of Candidate Immunologic Biomarkers and Surrogate Markers Alan Landay, Ph.D.
- How These Markers Relate to Disease Pathophysiology Clifford Lane, M.D.
- Clinical Studies –Where Are We and Where Do We Go from Here? Donna Mildvan, M.D.
- 10:30 Break**
- 10:45 Issues and Considerations for the Development of Biomarkers and Surrogate Markers**
- Perspective on Viral Load and CD4 T Cell Counts Daniel R. Kuritzkes, M.D.
- Perspective on Other Markers of Immune Function Michael Lederman, M.D.
- Limitations and Complexities of Biomarkers and Surrogate Markers Thomas R. Fleming, Ph.D.
- 12:00 Lunch**
- 1:00 Open Public Hearing**
- 2:00 Discussion and Questions to the Committee:**
- Utility of Outcome Measures Using HIV Viral Load, CD4 Cell Counts, and Other Immunologic Markers as Biomarkers and Surrogate Markers for Immune Based Therapies for HIV
- 4:30 Summary and Wrap-up** William D. Schwieterman, M.D.
- 5:00 Adjourn**